

LISTING OF THE CLAIMS

1. (Previously Presented) A transmucosally delivered controlled release composition which upon administration exhibits substantially linear absorption rates, the composition comprising:

(a) an analgesically effective amount of morphine;

(b) a controlled release chitosan polymer in an amount effective to provide substantially linear absorption rates upon administration;

(c) an antimicrobial agent selected from benzalkonium chloride, disodium EDTA, or a combination thereof;

and optionally further comprising:

(d) one or more antioxidants; and

(e) water;

wherein the molecule to molecule ratio of morphine to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide substantially linear absorption rates upon administration.

2. (Previously Presented) The composition of claim 1, wherein the molecule to molecule ratio of the morphine to the controlled release chitosan polymer ranges from about 5,000:1 to about 80,000:1.

3. (Canceled)

4. (Previously Presented) The composition of claim 1, wherein the concentration of morphine is from about 18.75 mg/ml to about 300 mg/ml.

5. (Previously Presented) The composition of claim 1, wherein the concentration of morphine is from about 37.5 mg/ml to about 150 mg/ml.

6. (Previously Presented) The composition of claim 1, wherein the morphine is purified morphine.

7. (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 2 mg/ml to about 7 mg/ml.

8. (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 4 mg/ml to about 6 mg/ml.

9. (Original) The composition of claim 1 wherein the antioxidant is selected from the group consisting of methanesulfonic acid, citric acid, sodium citrate, ascorbic acid, and sodium ascorbate.

10. (Previously Presented) The composition of claim 9, wherein the antioxidants are selected from the group consisting of citric acid and sodium citrate, and the total amount of antioxidant is present in a range from about 20 to about 50 mg/ml of the composition.

11. (Previously Presented) The composition of claim 9, wherein the antioxidants are selected from the group consisting of ascorbic acid and sodium ascorbate, and the total amount of antioxidant is present in a range from about 40 to about 70 mg/ml of the composition.

12. (Previously Presented) The composition of claim 9, wherein the antioxidant is methanesulfonic acid, and the amount of antioxidant is present in a range from about 10 to about 60 mg/ml of the composition.

13. (Previously Presented) The composition of claim 1, wherein the antimicrobial agent further comprises sodium benzoate.

14. (Previously Presented) The composition of claim 1, wherein the antimicrobial agent is at a concentration of from about 0.0005% to about 0.5% by weight/volume of the composition.

15. (Previously Presented) The composition of claim 1, wherein the concentration of antimicrobial agent is from about 0.005% to about 0.5% by weight/volume of the composition.

16. (Original) The composition of claim 1, wherein the transmucosal delivery is selected from the group consisting of nasal, buccal, rectal, vaginal, and ocular modes of administration.

17. (Original) The composition of claim 1, wherein the transmucosal delivery is by nasal administration.

18. (Withdrawn) The composition of claim 1, wherein the composition is prepared under nitrogen gas by

(a) mixing the morphine and acid, polymer, and antimicrobial agents, wherein each ingredient is mixed into the solution for at least 5 minutes;

(b) adding the antioxidants, wherein the pH is from about 3.0 to about 5.0;

(c) adjusting the final batch volume with water to form a final solution; and

(d) filtering the solution with a pre-sterilized micron filter.

19. (Withdrawn) The composition of claim 18, wherein the pre-sterilized micron filter is about a 0.2 micron filter.

20. (Previously Presented) The composition of claim 1, wherein the composition yields about 18.75 to about 300 microgram of morphine per 100 microliter nasal spray.

21. (Previously Presented) A method of administering a controlled release morphine medicament which upon administration exhibits substantially linear absorption rates, wherein the medicament is administered transmucosally to a subject in need thereof, said medicament comprising:

(a) an analgesically effective amount of morphine;
(b) a controlled release chitosan polymer in an amount effective to provide substantially linear absorption rates upon administration;
(c) an antimicrobial agent selected from benzalkonium chloride, disodium EDTA, or a combination thereof;
and optionally comprising:
(d) one or more antioxidants; and
(e) water
wherein the molecule to molecule ratio of morphine to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide substantially linear absorption rates upon administration.

22. (Previously Presented) The method of claim 21, wherein the morphine is purified morphine.

23. (Original) The method of claim 21, wherein the subject is human.

24. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the weight ratio of morphine:chitosan is about 7.5:1.

25. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the weight ratio of morphine:chitosan is about 15:1.

26. (Previously Presented) A transmucosally delivered controlled release composition which upon administration exhibits substantially linear absorption rates, the composition comprising:

(a) an analgesically effective amount of morphine;
(b) a controlled release chitosan polymer in an amount effective to provide substantially linear absorption rates upon administration;
(c) an antimicrobial agent selected from benzalkonium chloride, disodium EDTA, or a combination thereof;

and optionally comprising:

(d) one or more antioxidants; and

(e) water;

wherein the molecule to molecule ratio of morphine to the controlled release chitosan polymer ranges from about 1:1 to about 23,000:1 to provide the substantially linear absorption rates upon administration.

27. (Previously Presented) The transmucosally delivered controlled release composition of claim 26, wherein the molecule to molecule ratio of morphine to the controlled release chitosan polymer is about 11,500:1.

28. (Previously Presented) The transmucosally delivered controlled release composition of claim 26, wherein the molecule to molecule ratio of morphine to the controlled release chitosan polymer is about 23,000:1.

29. (Previously Presented) The transmucosally delivered controlled release composition of claim 26, wherein the pH is from about 3.0 to about 7.0.

30. (Previously Presented) The transmucosally delivered controlled release composition of claim 29, wherein the pH is from about 4.0 to about 5.0.

31. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the pH is from about 3.0 to about 7.0.

32. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the pH is from about 4.0 to about 5.0.

33. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the morphine is morphine mesylate.

34. (Previously Presented) The transmucosally delivered controlled release composition of claim 1, wherein the controlled release chitosan polymer is chitosan.

35. (Previously Presented) The transmucosally delivered controlled release composition of claim 26, wherein the morphine is morphine mesylate.

36. (Previously Presented) The transmucosally delivered controlled release composition of claim 26, wherein the controlled release chitosan polymer is chitosan.